

REMARKS

The specification has been reviewed for and amended to correct informalities such as typographical and grammatical errors.

Claims 1-12 and 50-59 were pending in this application. Claims 1, 3-8, and 50-58 have been amended. Claims 13-49 were previously canceled and claim 59 is canceled herein. Claims 3, 5, 7, 52, and 56 have been withdrawn from further consideration by the Examiner as being drawn to a non-elected invention. New claims 60-65 have been added. Accordingly, upon entry of this amendment, claims 1-12, 50-58, and 60-65 will be pending.

Any amendments to and/or cancellation of the claims are not to be construed as acquiescence to any of the rejections set forth in the instant Office Action, and were done solely to expedite prosecution of the application. Applicants hereby reserve the right to pursue the subject matter of the claims as originally filed in this or a separate application(s).

Support for the amendments to the claims may be found throughout the specification and claims, as originally filed. *No new matter has been added.* Specifically, support for the amendments to claims 4-7 and 52-53 to recite “consensus T-box site” can be found, for example, at page 8, lines 4-5, page 14, lines 20-23, and Example 3, page 64, lines 15-35 of the specification; support for the amendments to claims 4-7 to recite “90%” can be found, for example, at page 15, lines 20-28; support for the amendments to claim 50, can be found, for example, at page 14, line 27, through page 15, lines 1-3 and page 39, lines 6-10; support for new claim 60 can be found, for example, at page 34, lines 34-36; support for new claims 61-63 can be found, for example, at page 45, line 37, through page 46, lines 1-4; support for new claim 664 can be found, for example, at page 40, lines 23-26; and support for new claim 65 can be found, for example, at page 9, lines 21-25.

Election/Restriction

The Examiner acknowledges Applicants’ election with traverse of Group I (claims 1, 2, 4, 6, and 8-12, drawn to isolated nucleic acid molecules encoding human T-bet proteins, vectors, host cells and, methods of producing the protein) in the Amendment and Response filed October

Amendments To The Drawings

The attached sheet(s) of drawings includes changes to the two of Figure 1A and the four of Figure 1B. The two of Figure 1A have been relabeled to be identified as “Figure 1A” and “Figure 1B” and the four of Figure 1B have been relabeled to be identified as “Figure 1C”, “Figure 1D”, “Figure 1E”, and “Figure 1F”.

Figures 1A-1F have also been amended to include the appropriate sequence identifiers.

Attachment: Replacement sheet
 Annotated sheet showing changes

25, 2004 which the Examiner indicates has necessitated a further restriction to one of the following inventions under 35 U.S.C. §121:

Group I. Claims 1, 2, 4, 6, 8 - 12, 50 - 55, and 57 - 59, drawn to an isolated nucleic acid encoding human T-bet protein, as well as vectors, host cells, and methods of producing the protein, classified in Class 536, subclass 23.5; Class 435, subclasses 69.1, 455, 252.3, and 320.1.

Group II. Claims 1, 3, 5, 7, 8 - 12, 50 - 52, 54, 56, and 57 drawn to an isolated nucleic acid encoding murine T-bet protein, as well as vectors, host cells, and methods of producing the protein, classified in Class 536, subclass 23.5; Class 435, subclasses 69.1, 455, 252.3, and 320.1.

The Examiner states that “Groups I and II are different products. The claimed nucleic acids differ with respect to their structures and physicochemical properties and require non-coextensive searches, therefore each product is patentably distinct.”

Applicants’ respectfully traverse the foregoing Restriction Requirement and submit that the requirement is improper in that a species election between human and murine nucleic acid molecules encoding T-bet should be required for search purposes. Applicants’ reiterate their position that the human and murine T-bet nucleic acid molecules are structurally related, sharing 85.7% identity. In addition, these human and murine molecules share a common function, binding to T box binding domains present in DNA. Moreover, Applicants respectfully submit that the search of nucleic acid molecules encoding murine T-bet proteins (claims 1, 3, 5, 7, 8-12, 50-52, 54, 56, and 57) would be coextensive with a search for nucleic acid molecules encoding human T-bet proteins (claims 1, 2, 4, 6, 8-12, 50-55, and 57-59 directed to human T-bet nucleic acid molecules), and would not place a burden on the Examiner (see M.P.E.P. § 803).

Applicants acknowledge the Examiner’s indication that claims 51 and 52 link the species of Groups I and II. It is Applicants understanding that upon allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination.

In order to be considered responsive to the instant Office Action, Applicants’ hereby elect the Group I (claims 1, 2, 4, 6, and 8-12, 50-55, and 57-59) species *with traverse* for prosecution on the merits should no linking claim be found allowable.

Sequence Disclosure

The Examiner states that the application fails to comply with the requirements of 37 C.F.R. §1.821 through C.F.R. §1.825, because “the sequences disclosed at least on pages 64 and 72 and in Figure 1 are *not accompanied by SEQ ID Numbers*.”

Applicants have amended the specification to add sequence identifiers on pages 64 and 72 as well as to the sequences depicted in Figures 1A-1F. Applicants submit herewith a substitute sequence listing and amended drawings, and accordingly request reconsideration and withdrawal of the rejection under C.F.R. §1.821- C.F.R. §1.825.

Priority

The Office Action acknowledges the claim for domestic priority under 35 U.S.C. §119(e) and §120, and states that “[t]he priority applications USSN 60/137,085 and PCT/US00/15345 appear to provide adequate support under 35 U.S.C. § 112 for the subject matter of claims 1, 2, 4, 6, 8-12, 51, 53-55, and 57-59. However, the Examiner is also of the opinion that “the priority applications fail to provide adequate support under 35 U.S.C. § 112 for claim 50 of this application. Specifically, insufficient support was identified for the limitation of ‘IFN- γ production, Th1-associated cytokine production, and Th1 cell differentiation.’ Consequently, the claim has been accorded the priority of the filing date of the instant application, *i.e.* 12/03/2001.”

Applicants respectfully traverse the Examiner’s assertion that claim 50 (the limitation of IFN- γ production, Th1-associated cytokine production, and Th1 cell differentiation) is not supported by the priority documents, U.S. Provisional Application No. 60/137,085, filed June 2, 1999, and PCT/US00/15345, filed June 1, 2000, for the reasons set forth below.

Specifically, Applicants point the Examiner to at least the following pages in U.S. Provisional Application No. 60/137,085 for support. At page 4, lines 18-27, the specification of that application teaches that

This invention is based, at least in part, on the discovery of novel compositions which act to promote the Th1 phenotype in naïve T helper precursor cells (Thp), both by *initiating Th1 cell genetic programs* and by repressing the opposing programs in Th2 cells. In particular, this invention provides isolated nucleic acid

molecules encoding T-bet and isolated T-bet protein. T-bet (T box expressed in T cells) is a new member of the T box family of transcription factors whose founding member is the *brachyury* gene. T-bet is constitutively expressed selectively in thymocytes and Th1 cells. T-bet is the first Th1 specific transcription factor that can transactivate the interferon-gamma gene, ***induce interferon-gamma production*** in retrovirally transduced primary T cells and redirect polarized Th2 cells into the Th1 pathway.

At page 16, lines 2-12, the specification teaches that

[t]he expression of T-bet correlates with IFN- γ expression in Th1 cells, NK cells and B cells, and T-bet is a potent transactivator of the IFN- γ gene. Most convincing, retroviral mediated transduction of Thp, Th1 and polarized Th2 and Tc2 cells with T-bet results in an impressive ***induction of IFN- γ*** expression. This is accompanied by repression of both IL-2 and IL-4 production. Thus, the function of T-bet extends beyond the simple control of IFN- γ gene transcription. T-bet converts both polarized effector Th2 cells and polarized Tc2 cells into the opposing Th1 and Tc1 subsets, respectively. Taken together, these data demonstrate that T-bet is responsible for the genetic program that ***initiates Th1 lineage development*** from naïve Thp cells and acts both by initiating Th1 genetic programs and by repressing the opposing programs in Th2 cells

At page 42, lines 25-29, the specification teaches that

Specific embodiments of the screening methods of the invention exploit the ability of T-bet proteins to bind to DNA (e.g., the ability to bind to an IL-2 or IFN-gamma promoter) and/or to regulate gene expression (e.g., ***regulate expression of a Th1-associated cytokine gene***, e.g., by repressing the IL-2 gene, transactivate the IFN- γ gene) and/or to ***redirect polarized Th2 cells into the Th1 pathway***.

Applicants also point the Examiner to the working Examples in the specification of U.S. Provisional Application No. 60/137,085. Specifically, Example 5 (page 73, line 28, though page 74, lines 1-28) teaches that ***T-bet initiates Th-1 cytokine production***; Examples 5-7 (page 73, line 28, through page 77, lines 1-31) teach that ***T-bet transactivates the IFN- γ gene*** in multiple cell types and ***induces IFN- γ production*** in retrovirally transduced primary T cells; and Examples 8-10 (page 78, line 2, through page 79, lines 1-17) teach that ***T-bet initiates Th1 cell differentiation*** in naïve and differentiated cells.

Accordingly, Applicants submit that there is more than sufficient support for the recitation of IFN- γ production, Th1-associated cytokine production, and Th1 cell differentiation in the priority documents and request reconsideration by the Examiner and that claim 50 be accorded the priority date of U.S. Provisional Application No. 60/137,085, *i.e.*, June 2, 1999.

Title

The Examiner states that the title of the invention is not descriptive and requires a new title “clearly indicative of the invention *to which the claims are directed*.”

Applicants respectfully submit that the current claims are directed to T-bet nucleic acid molecules, *e.g.*, T-bet compositions and uses therefore. Specifically, claims 1-10 and 50-58 and directed to T-bet compositions, *e.g.*, T-bet nucleic acid molecules, and claims 11-12 are directed to uses of T-bet nucleic acid molecules. Therefore, the current title, T-BET COMPOSITIONS AND METHODS OF USE THEREOF, is descriptive of the invention. Accordingly, Applicants request reconsideration and withdrawal of the objection to the title.

Specification

The specification has been objected to because “it contains an embedded hyperlink or other form of browser-executable code, *e.g.* on page 9.” “See MPEP 608.01.”

Applicants respectfully submit that the inclusion of web-addresses in the specification is directed to nonessential material. The disclosed hyperlinks are merely illustrative of well-known methods for comparing nucleotide and amino acid sequences that are readily accessible to one of ordinary skill in the art. The methods used by Applicants are also disclosed by reference to published documents (*e.g.*, Altschul, *et al.* (1990) *J. Mol. Biol.* 215:403-10.). Further, the specific programs and software are disclosed and the particular parameters (*e.g.*, gap weight, length weight, scoring matrix, *etc.*) are also recited in the Detailed Description. Accordingly, the specification has now been amended to delete reference to this hyperlink, and withdrawal of this objection is requested.

Claim Objections

The Examiner has objected to claim 6 as being in improper dependent format. Claim 6 has been re-written in independent format rendering the Examiner’s objection moot.

The Examiner has also objected to claims 1, 51, 55, 58, and 59 for not using the proper format for sequence identifiers. Claim 59 has been canceled and claims 1, 51, 55, and 58 have been amended using the format, "SEQ ID NO:X" thereby rendering the Examiner's objection moot.

Accordingly, Applicants request reconsideration and withdrawal of the foregoing claim objections.

Rejection of Claims Under 35 U.S.C. §112, Second Paragraph

The Examiner has rejected claims 4, 6, 8-12, 51, 53, and 54 under 35 U.S.C. §112, first paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. In particular the Examiner is of the opinion that the recitation of the term "a T-box binding element in DNA" is vague and indefinite. The Examiner states that "[a]lthough the specification mentions in several instances 'T-box binding sites' (e.g. on pages 13 and 41), and provides an exemplary sequence of a consensus T-box binding site on page 72, characteristics of a broadly claimed 'T-box binding element' are not defined. Thus one of ordinary skill in the art would not be reasonably apprised of the metes and bounds of the invention."

Applicants respectfully traverse this rejection, however in the interest of expediting the prosecution of the application have amended claims 4, 6, 51, 53, and claims dependent therefrom, to recite "***consensus T-box site***" rendering the Examiner's rejection moot.

Accordingly, Applicants request reconsideration and withdrawal of the foregoing rejection of claims 4, 6, 8-12, 51, 53, and 54.

The Examiner has rejected claim 50 under 35 U.S.C. §112, first paragraph, as being indefinite. In particular, the Examiner is of the opinion that claim 50 is indefinite for the "recitation of 'activity selected from the group consisting of IFN- γ production, Th1-associated cytokine production, and Th1 cell differentiation' because it is ambiguous as to

whether the claimed activity is directed to increasing or decreasing said production or differentiation. Thus the metes and bounds of the claimed Invention are not defined.”

Applicants respectfully traverse this rejection, however in the interest of expediting prosecution of the present application have amended claim 50 to recite “the activity selected from the group consisting of, **induction** of IFN- γ production, **induction** of Th1-associated cytokine production, and **initiation** of Th1 cell differentiation” rendering the Examiner’s rejection moot.

Accordingly, Applicants request reconsideration and withdrawal of the rejection of claim 50.

The Examiner has also rejected claim 50 under 35 U.S.C. §112, first paragraph, as being indefinite in the recitation of Th1 cell differentiation, because the term is vague. The Examiner is of the opinion that “[i]t is unclear whether the claim is directed to T-bet activity to ‘redirect polarized Th2 cells into the Th1 pathway’ (specification on page 39 second paragraph), to an initial commitment of T cells towards the Th1 pathway, or to some other aspect of complex and multifaceted process of T cell development.”

Applicants respectfully traverse this rejection and submit that as disclosed in the present specification, T-bet is “**a key regulator of the development of Th1 cells**” (page 52, line 4); T-bet modulates not only the development of naïve T cells into Th1 cells (see, for example, page 4, lines 4-7 and page 14, line 37, through page 15, lines 1-3); and developing Th2 cells, *e.g.*, polarized effector Th2 cells, into Th1 cells (see, for example, page 4, lines 10-14; page 14, lines 32-37; and Example 9, page 70, lines 18-36), but can also redirect fully polarized Th2 cells into Th1 cells (see, for example, Example 10, page 71, lines 1-10). Furthermore, T-bet activity represses the opposing Th2 cell developmental programs.

Nonetheless, in order to expedite prosecution, Applicants have amended claim 50 to recite “**initiation of Th1 cell differentiation of Thp cells and Th2 cells**” rendering the Examiner’s rejection moot.

Accordingly, Applicants respectfully request reconsideration and withdrawal of the foregoing rejection of claim 50.

Rejection of Claims Under 35 U.S.C. §112, First Paragraph

The Examiner has rejected claims 4, 6, 8-12, 50, and 54 under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. *This is a new matter rejection.*

Specifically, the Examiner is of the opinion that the “specification does not appear to provide an adequate written description of ‘at least 95% identity’ as it applies to nucleic acid sequence.”

Applicants have amended claims 4, 6, and claims dependent therefrom to recite that the nucleic acid molecules are ***at least 90% identical*** to SEQ ID NO:1, thereby obviating this rejection. Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection of claims 4, 6, 8-12, 50, and 54 under 35 U.S.C. §112, first paragraph.

The Examiner has rejected claim 53 under 35 U.S.C. §112, first paragraph, as not providing adequate written description “of ‘at least about 95% identity’ as it applies to the amino acid sequence.”

Applicants have amended claim 53 to recite that the polypeptide comprises an amino acid sequence ***at least 95% identical*** to the amino acid sequence of SEQ ID NO:2, thereby obviating this rejection. Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection of claim 53 under 35 U.S.C. §112, first paragraph.

The Examiner has rejected claim 50 under 35 U.S.C. §112, first paragraph for the recitation of “Th1 cell differentiation” as being “broader in scope than originally presented, as it encompasses other cellular processes, such as the initial commitment of cells towards the Th1 pathway.”

Applicants respectfully traverse this rejection and submit that recitation of “Th1 cell differentiation” as an activity of T-bet is not broader in scope than originally presented. As stated above, T-bet is a key regulator of the development of Th1 cells that modulates not only the development of naïve T cells into Th1 cells, developing Th2 cells into Th1 cells,

fully polarized Th2 cells into Th1 cells, but also represses the opposing developmental programs of Th2 cells. Even so, in order to expedite prosecution, Applicants have amended claim 50 to recite “*initiation of Th1 cell differentiation of Thp cells and Th2 cells*” rendering the Examiner’s rejection moot.

Accordingly, Applicants respectfully request reconsideration and withdrawal of the foregoing rejection of claim 50.

Claim 59 has been rejected by the Examiner under 35 U.S.C. §112, first paragraph as “there appears to be insufficient direction to a fragment comprising specifically nucleotides 1-900” of SEQ ID NO:1.

Applicants have canceled claim 59 thereby rendering this rejection moot.

Claim 50 has been rejected by the Examiner under 35 U.S.C. §112, first paragraph, because the specification does not enable any person skilled in the art to which it pertains, or with which it is most clearly connected, to make and use the invention commensurate in scope with these claims. Specifically, the Examiner states that “the specification, while being enabling for a polypeptide that has the activity of [inducing] IFN- γ production in CD4+ cells, does not reasonably provide enablement for a broad recitation of a peptide that has the activity of [inducing] IFN- γ production.”

Applicants have amended claim 50 to recite that the polypeptide *induces IFN- γ production in CD4+ cells*, rendering the rejection moot. Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection of claim 50 under 35 U.S.C. §112, first paragraph.

The Examiner has rejected claims 55 and 57 under 35 U.S.C. §112, first paragraph, “because the specification, while being enabling for an isolated nucleic acid consisting of a fragment of at least 700 contiguous nucleotides of the nucleotide sequence of SEQ ID NO:1 or complement thereof, or, alternatively, comprising the sequence of SEQ ID NO:1, does not reasonably provide enablement for an isolated nucleic acid comprising a fragment of at


least 700 contiguous nucleotides of the nucleotide sequence of SEQ ID NO:1 or complement thereof.”

Applicants have amended independent claim 55 to recite “an isolated nucleic acid *consisting of a fragment* of at least 700 contiguous nucleotides of the nucleotide sequence of SEQ ID NO:1” rendering the rejection moot. Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection of claim 55 and dependent claim 57 under 35 U.S.C. §112, first paragraph

Rejection of Claims Under 35 U.S.C. §102

Claims 1, 2, 4, 6, 51, 53, 55, 58, and 59 have been rejected under 35 U.S.C. §102(a) as being anticipated by Yang (of record, GenBank Accession No. AF093098). Specifically, the examiner states that “Yang teaches a polypeptide which is 100% identical to the instantly claimed SEQ ID NO:2, and a nucleic acid sequence encoding said polypeptide which includes a region 100% identical to SEQ ID NO:1.”

The examiner has also rejected claim 50 under 35 U.S.C. §102(b) as being anticipated by Yang (of record, GenBank Accession No.). Specifically, the Examiner states that “Yang teaches a polypeptide which is 100% identical to the instantly claimed SEQ ID NO:2, and a nucleic acid sequence encoding said polypeptide which includes a region 100% identical to SEQ ID NO:1. As the sequence of the protein taught by Yang is identical to that of the instantly claimed protein, all of its functional properties are inherently the same. Since claim 50 has been accorded the priority date of the instant application, i.e. 12/03/2001, the rejection is set forth under 35 U.S.C. 102(b) rather than 102(a).”

Applicants respectfully traverse the foregoing rejections under 35 U.S.C. §102 and submit that the Yang, *et al.* reference is not available as a prior art reference under either 35 U.S.C. §102(a) and/or 35 U.S.C. §102(b). Specifically, the priority date of the Yang reference cited by the Examiner as September 17, 1998 is merely the date that a record at GenBank was opened, *e.g.*, as a placeholder. The date that the sequence disclosed in the Yang reference was first available as a public disclosure, *i.e.*, the publication date, was October 1, 1999. Therefore, the reference was published after the June 2, 1999 priority date of the instant application. In support of this, Applicants submit the Revision History of AF093098 (Yang) in Appendix A. 

Furthermore, with respect to claim 50, as stated above, Applicants maintain that the subject matter of claim 50 should be accorded the priority date of the instant application, *e.g.*, June 2, 1999, and thus Yang, *et al.* is not available as a prior art reference under either 35 U.S.C. §102 and/or 35 U.S.C. §103.

Applicants, therefore, respectfully request reconsideration and withdrawal of the foregoing rejection of claims 1, 2, 4, 6, 50, 51, 53, 55, 58, and 59 under 35 U.S.C. §102.

Rejection of Claims 34-37 and 41-43 Under 35 U.S.C. §103(a)

The Examiner has rejected claims 8-12 under 35 U.S.C. §103(a) as being unpatentable over Kishimoto, *et al.* (US Pat. No. 5,844,082; see entire document) in view of Yang (of record).

Specifically, the Examiner states that

Kishimoto, *et al.* teach nucleic acids encoding a transcription factor, as well as expression vectors and host cells comprising said nucleic acids, and methods of producing the transcription factor by culturing host cells (see entire document, in particular, column 5 line 55 - column 6 line 18).” Yang has been discussed *supra*, and teaches a human transcription factor which is 100% identical to the instantly claimed T-bet transcription factor of SEQ ID NO:2, and a nucleic acid sequence encoding said transcription factor which includes a region 100% identical to instantly claimed SEQ ID NO:1.

One of ordinary skill in the art at the time the invention was made would have been motivated to express the T-bet transcription factor of the instant Invention by placing the respective nucleic acids into an expression vector and further into a host cell, and to express the protein by culturing the cells, because Kishimoto *et al.* teach that expressing a transcription factor may be useful for treatment of diseases (see entire document, in particular, *e.g.* the Abstract). Furthermore, one of ordinary skill in the art at the time the invention was made would have had a reasonable expectation of success, because these methods were routinely used at the time, as evidenced by Kishimoto *et al.* in the phrase “by each method commonly used” when referring to introduction of a vector into host cells (column 6 line 3) as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Applicants respectfully traverse this rejection, and submit, as stated above, the Yang reference is not available as a prior art reference under 35 U.S.C. §102 and/or 35 U.S.C. §103.

Furthermore, to establish a *prima facie* case of obviousness, it is necessary for the Examiner to present evidence, preferably in the form of some teaching, suggestion, incentive or inference in the applied references, or in the form of generally available knowledge, that one having ordinary skill in the art would have been motivated to make the claimed invention and would have had a reasonable expectation of success in making the claimed invention. Under section 103, "[b]oth the suggestion and the expectation of success must be founded in the prior art, not in applicant's disclosure" (*Amgen, Inc. v. Chugai Pharmaceutical Co., Ltd.* 927 F.2d 1200, 1207, 18 USPQ2d 1016 (Fed. Cir. 1991), quoting *In re Dow Chemical Co.*, 837 F.2d 469, 473, 5 USPQ2d 1529, 1531 (Fed Cir. 1988)). Moreover, when a combination of references are used to establish a *prima facie* case of obviousness, the Examiner must present evidence that one having ordinary skill in the art would have been motivated to combine the teachings in the applied references in the proposed manner to arrive at the claimed invention. See, e.g., *Carella v. Starlight Archery*, 804 F.2d 135, 231 USPQ 644 (Fed. Cir. 1986); and *Ashland Oil, Inc. v. Delta Resins and Refractories, Inc.*, 776 F.2d 281, 227 USPQ 657 (Fed. Cir. 1985). **Finally, the prior art reference (or references when combined) must teach or suggest all of the claim limitations** (M.P.E.P. 2143).

As stated above, Yang, is unavailable as a prior art reference. Applicants respectfully submit that Kishimoto, *et al.* fails to teach each and every limitation of the claimed invention. Claim 8 and the claims dependent therefrom are directed to vectors comprising the nucleic acid molecules comprising **the nucleotide sequence of SEQ ID NO:1** (claims 2, 4, 6, 51, 53, 55, and 57), **SEQ ID NO:3** (claims 3, 5, 7, 52, and 56), or a nucleotide sequence encoding the polypeptide of **SEQ ID NO:2** (claim 1). Kishimoto, *et al.* fail to teach or suggest the nucleotide sequence of SEQ ID NO:1, the nucleotide sequence of SEQ ID NO:3 or a nucleotide sequence encoding the polypeptide of SEQ ID NO:2.

Therefore, for the reasons set forth above, Kishimoto, *et al.* fails to teach or suggest each and every element of the claimed invention. Accordingly, Applicants respectfully request reconsideration and withdrawal of the foregoing rejection.

Rejection of Claims, Double Patenting

The Examiner has provisionally rejected claims 1, 2, 4, 6, 8-12, 50, 51, 53-55, and 57-59 under the judicailly created doctrine of obviousness-type double patenting as being “unpatentable over claims 1, 11, 12, 14, 19, and 22 of copending Application USSN 10/309,747, published as US Pat. Pub. No. 2003/0186377.” The Examiner states that [c]laims 1, 11, 12, 14, 19, and 22 of USSN 10/309,747 are drawn to a nucleic acid encoding a T-bet polypeptide, a vector comprising said nucleic acid, and a method of producing said polypeptide by culturing a host cell comprising said vector.” The Examiner continues, [a]lthough the conflicting claims are not identical, they are not patentably distinct from each other because they are drawn to the same or nearly the same nucleic acids encoding a T-bet protein, as well as vectors and methods of producing the polypeptide.”

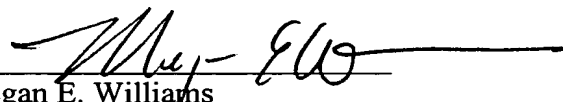
Applicants respectfully submit that upon an indication of allowable subject matter in this or the related applications Applicants will consider filing a terminal disclaimer, if appropriate.

SUMMARY

If a telephone conversation with Applicants' Attorney would expedite the prosecution of the above-identified application, the Examiner is urged to call Applicants' Attorney at (617) 227-7400.

Dated: July 22, 2005

Respectfully submitted,

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